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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/413,785	10/07/1999	STAVROS C. MANOLAGAS	D6156	2424

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EXAMINER
BAKER, ANNE MARIE

ART UNIT	PAPER NUMBER
1632	15

DATE MAILED: 03/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/413,785	Applicant(s) MANOLAGAS ET AL.	
	Examiner Anne Baker	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,15,20,21 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,15,20,21 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *13* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

The amendment filed January 4, 2002 (Paper No. 12) has been entered. Claims 2-5, 15, 20, and 21 have been amended. Claims 1, 16, 22, and 23 have been cancelled.

Accordingly, Claims 2-5, 15, 20, 21, and 24 remain pending in the instant application.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous Office Action are hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 5, 21, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Lane et al. (1995).

The claims are directed to a method of increasing the lifespan of osteoblasts in a bone-containing host in need of preventing bone loss or stimulating bone formation by administering at least 10 μg per kilogram body weight of parathyroid hormone fragment (1-34).

While the preamble of the claims recite "increasing the lifespan of osteoblasts," this phrase is given no patentable weight, as the specification clearly discloses that the purpose of administering PTH is to stimulate bone formation (page 18, lines 19-20 of specification).

Lane et al. (1995) disclose that intermittent administration of hPTH(1-34) at 40 μg/kg body weight and 400 μg/ kg body weight, to osteopenic rats, resulted in increased trabecular bone volume (Abstract and page 1471, column 2, paragraph 1). The reference further discloses that intermittent PTH injections appear to increase bone mass by adding bone to existing trabeculae (page 1470, column 2, paragraph 1). Thus, an increase in trabecular bone volume would clearly correlate with an increase in bone mass.

Thus, the claimed invention is disclosed in the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 4, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane et al. (1995) and Finkelstein et al. (1998).

The claims are directed to a method of increasing the lifespan of osteoblasts in a bone-containing host in need of preventing bone loss or stimulating bone formation by administering at least 10 μg per kilogram body weight of parathyroid hormone fragment (1-34).

Lane et al. (1995) disclose that intermittent administration of hPTH(1-34) at 40 μg/kg body weight and 400 μg/ kg body weight, to osteopenic rats, resulted in increased trabecular bone volume (Abstract and page 1471, column 2, paragraph 1). The reference further discloses that intermittent PTH injections appear to increase bone mass by adding bone to existing trabeculae (page 1470, column 2, paragraph 1). Thus, an increase in trabecular bone volume would clearly correlate with an increase in bone mass.

Finkelstein et al. (1998) disclose a method for preventing bone loss in humans by the subcutaneous administration of parathyroid hormone-(1-34). The dose disclosed by Finkelstein et al. is 40 μg, administered subcutaneously. The reference also discloses that intermittent PTH administration can completely reverse established osteopenia.

Although Finkelstein et al. (1998) disclose administration of the parathyroid hormone fragment by subcutaneous injection, one of skill in the art would have been motivated to consider other modes of administration and would have anticipated a reasonable expectation of success in finding alternate modes of administration as only routine experimentation is required to extend the invention of Finkelstein et al. from the subcutaneous mode of administration to other modes of administration.

One of skill in the art would have recognized that the disclosure of Lane et al. in combination with Finkelstein et al. demonstrates that doses of PTH(1-34) that are significantly higher than that used by Finkelstein et al. are effective in increasing bone mass. Thus, one of skill in the art would have been motivated to combine the teachings of Lane et al. (1995) and Finkelstein et al. (1998).

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leaffer et al. (1995) and Finkelstein et al. (1998).

Claim 20 is directed to a method of increasing the lifespan of osteoblasts in a bone-containing host in need of preventing bone loss or stimulating bone formation by administering at least 10 μg per kilogram body weight of bovine parathyroid hormone fragment (1-34).

Leaffer et al. (1995) disclose the administration of bovine parathyroid fragment (1-34) at 80 μg/kg of body weight (Abstract and page 3625, column 1, paragraph 1). The reference further discloses that PTH and its N-terminal 1-34 or 1-38 fragments act as anabolic agents on cancellous bone when administered as daily subcutaneous injections (page 3624, column 1, paragraph 1). The reference further discloses that, after 19 days of treatment, the bone calcium in the treatment groups increased compared to that in the ovariectomized vehicle-treated controls (page 3626, column 1, paragraph 1).

Finkelstein et al. (1998) disclose a method for preventing bone loss in humans by the subcutaneous administration of parathyroid hormone-(1-34). The dose disclosed by Finkelstein et al. is 40 μg, administered subcutaneously. The reference also discloses that intermittent PTH administration can completely reverse established osteopenia.

Although Finkelstein et al. (1998) disclose administration of the parathyroid hormone fragment by subcutaneous injection, one of skill in the art would have been motivated to consider other modes of administration and would have anticipated a reasonable expectation of success in finding alternate modes of administration as only routine experimentation is required to extend the invention of Finkelstein et al. from the subcutaneous mode of administration to other modes of administration.

One of skill in the art would have recognized that the disclosure of Leaffer et al. in combination with Finkelstein et al. demonstrates that bovine parathyroid hormone (1-34) has the same *in vivo* biological activity as hPTH(1-34) and therefore could be used for administration to animal models to test a variety of therapeutic regimens involving PTH administration, for increasing bone mass or preventing bone loss. Thus, one of skill in the art would have been motivated to combine the teachings of Leaffer et al. (1995) and Finkelstein et al. (1998).

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Baker, Ph.D.

Anne-marie Baker

ANNE-MARIE BAKER
PATENT EXAMINER